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| 09/982,474 | 10/17/2001 | Wilhelmus Theodorus Antonius Maria De Laat | 246152012710 | 8056 |

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EXAMINER

WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1654

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,474

Applicant(s)

DE LAAT ET AL.

Examiner

RANDALL WINSTON

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3-8,15,16,19,20,36,37 and 52-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3-8,15,16,19,20,36,37 and 52-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-8, 15-16, 19-20, 36-37 and 52-63, in the response to the restriction requirement mailed July 15, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants expressly reserve their right under 35 U.S.C. 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application is also acknowledged. Claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 are presented for examination on the merits. (claim 2 has been cancelled by applicant)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 52 recite the phrase "contains only chemically defined components." No objective is provided in the specification or claim to apprise one of skill in the art of the meaning of "contains only chemically defined components." There is no definition of "contains only chemically defined components" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the

Art Unit: 1654

claimed invention because "contains only chemically defined components" can be interpreted various ways. (see, e.g. claims 3, 7, 52 and 56 112 2nd rejection below)

Claims 3, 7, 52 and 56 are rendered vague and indefinite by the term "and/or." Applicant is suggested to clarify the above term. (Does the fermentation medium contains only chemically defined components of carbon and nitrogen? or Does the fermentation medium contains only chemically defined components of carbon and/or nitrogen? The above claims are contradictory in reference to the above term. For example, claim 1 states the fermentation medium contains only carbon and nitrogen but claims 3, 7, 52, and 56 state the fermentation medium contains only carbon and/or nitrogen)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogye et al. (Derwent 1987-357537, abstract) in view of Bovenberg et al. (US 5731163) and Microbiology, fourth edition, Peleazar, Reid, and Chan pages 853-856.

Applicant claims a process for the production of Beta-Lactum comprising the steps of fermenting on a volume scale of at least 10 m³ a microbial stain (e.g. *Pencillium chrysogenum*) that produces a Beta-Lactam in a fermentation medium which is a chemically defined medium that contains only chemically defined components (e.g. components of a carbon and nitrogen source or carbon and/or nitrogen source--- see 112 2nd rejection above that this states the phrase "contains only chemically defined components" as being unclear), and recovering the Beta-Lactam.

Hogy teaches (see, e.g. abstract) a process for the production of Beta-Lactum (e.g. penicillin V) and its recovery comprising the steps of fermenting *Pencillium chrysogenum* that produces Beta-Lactum in a fermentation medium that contains only a chemically defined component of a nitrogen source such as ammonium sulphate and an ammonium hydroxide and the removal of the fermentation liquor to recover the Beta-Lactum

Hogy does not teach the process of the production of Beta-Lactum and its recovery comprising the steps of fermenting *Pencillium chrysogenum* that produces Beta-Lactum in a fermentation medium that contains only a chemically define component of a carbon source wherein the fermentation process produce Beta-Lactum at volume scale of at least 10m³.

Bovenberg et al. beneficially teach (see, e.g. example 1) a process for the production of Beta-Lactum (i.e. aidpoyl-7-ADCA) comprising the steps of fermenting *Pencillium chrysogenum* that produces Beta-Lactum in a fermentation medium that contains only a chemically define component of a carbon source.

Microbiology, pages 853-856, teaches that a Beta-Lactum (pencillin) was the first antibiotic to be produced industrially utilizing a similar standard chemically defined medium as the claimed invention's chemically defined medium (see, especially, e.g. page 855-856, the steps).

It would have been obvious to one of ordinary skill in the art of creating the claimed invention to modify Hogye' teaching and to include the beneficial teachings of Bovenberg and Microbiology because the above three combined reference teachings utilizing the same process steps would produce an improve process for the production of Beta-Lactum at an industrialized scale. Moreover, the difference in conventional result-effect conditions (fed-batch fermentation) does not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating such working condition(s) is/are critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g. MPEP 2144.05).

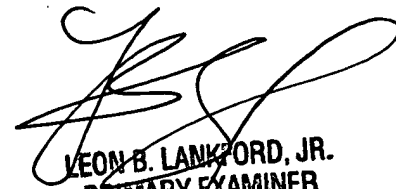
Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is 703-305-0404. The examiner can normally be reached on 8AM-5PM.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3110.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER